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Global 30-day outcomes after bariatric surgery during the COVID-19 pandemic (GENEVA): an international cohort study

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Bariatric and metabolic surgery (BMS) is the most effective intervention available for weight loss. However, the high morbidity and mortality associated with perioperative COVID-19[1] has led to the cancellation of millions of surgeries including BMS procedures. There are also concerns that obesity treatment, including BMS, might be especially overlooked in the COVID-19 recovery era due to obesity stigma,[2] leading the BMS community to develop recommendations for the management of candidates for BMS in the context of COVID-19.[3]

There is a paucity of data on the safety of BMS performed during the COVID-19 pandemic once the pandemic had become established and recognised. Therefore, we did an international cohort study (GENEVA) to investigate the 30-day morbidity and mortality of primary BMS done in adults (≥18 years) between May 1 and July 10, 2020. Complications were recorded by use of the Clavien-Dindo (CD) classification system, which is widely regarded as the accepted method for reporting surgical complications. Detailed methods are described in the appendix (pp 2–5).

2116 adult patients from 133 hospitals in 38 countries underwent primary BMS during the study period. Of these, 2001 (94·6%) patients, from 218 surgeons at 127 hospitals in 35 countries, had complete 30-day morbidity and mortality data available by Aug 15, 2020 (appendix p 6). Of the 35 countries with included patients, 12 had their peak incidence of COVID-19 before May 1, 2020 (883 patients [44·1%]); another 12 had their peak during the data collection period (811 patients [40·5%]); and the remaining 11 had their peak after Aug 10, 2020 (ie, after end of follow up; 307 patients [15·3%]; appendix p 7). Baseline demographic and clinical characteristics and types of surgery done are summarised in the appendix (p 8).

There was one death (18 days after surgery) in a patient who had a leak following sleeve gastrectomy (SG). This patient was COVID-19 negative. At 30 days, 138 complications were reported in 137 (6·8%) of 2001 patients, including ten cases of COVID-19 (table). Most complications (n=83 [60·6%]) were mild (CD grade I or II). Patients who developed complications tended to be older and were more likely to be current or ex-smokers (*vs* non-smokers). Fewer complications occurred with more experienced surgeons (appendix p 9).

There were ten (0·5%) symptomatic COVID-19 cases diagnosed during the 30-day follow-up. These were in Egypt (n=4), Brazil (n=2), Mexico (n=2), Argentina (n=1), and India (n=1; appendix p 10). Eight of these patients were from countries (Brazil, Egypt, and Mexico) that had their COVID-19 peak during the study period. Two of the ten patients had no preoperative testing for SARS-CoV-2, seven required no treatment, none needed intensive care or ventilation, and none died. 1593 (79·6%) of the 2001 patients in the study underwent some preoperative testing for COVID-19. Perioperative COVID-19 protocols in place during the study period are summarised in the appendix (p 11).

The overall 30-day mortality of 0·05% (1/2001) seen in this study is consistent with the pre-pandemic

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	All patients (n=2001)	SG (n=1142 [57%])	RYGB (n=557 [28%])	OAGB (n=215 [11%])	Other* (n=87 [4%])
Complications by CD classification system grade					
All complications	137 (6·8%)	65 (5·7%)	47 (8·4%)	19 (8·8%)	6 (6·9%)
CD grades I and II	83 (4·1%)	41 (3·6%)	29 (5·2%)	8 (3·7%)	5 (5·7%)
CD grades III, IV, and V	54 (2·7%)	24 (2·1%)	18 (3·2%)	11 (5·1%)	1 (1·1%)
CD grade I	42 (2·1%)	20 (1·8%)	17 (3·1%)	3 (1·4%)	2 (2·3%)
CD grade II	41 (2·0%)	21 (1·8%)	12 (2·2%)	5 (2·3%)	3 (3·4%)
CD grade IIIa	10 (0·5%)	3 (0·3%)	3 (0·5%)	4 (1·9%)	0
CD grade IIIb	29 (1·4%)	14 (1·2%)	9 (1·6%)	6 (2·8%)	0
CD grade IVa	12 (0·6%)	5 (0·4%)	6 (1·1%)	1 (0·5%)	0
CD grade IVb	2 (0·1%)	1 (0·1%)	0	0	1 (1·1%)
CD grade V (death)	1 (0·05%)	1 (0·1%)	0	0	0
COVID-19					
Symptomatic COVID-19	10 (0·5%)	8 (0·7%)	1 (0·2%)	0	1 (1·1%)
Specific complications					
Bleeding	36 (1·8%)	19 (1·7%)	11 (2·0%)	6 (2·8%)	0
Leak from gastrointestinal tract	16 (0·8%)	9 (0·8%)	2 (0·4%)	5 (2·3%)	0
Wound infection	10 (0·5%)	4 (0·4%)	4 (0·7%)	0	2 (2·3%)
Postoperative pneumonia (not otherwise specified)	5 (0·2%)	0	4 (0·7%)	1 (0·5%)	0
Deep vein thrombosis	1 (0·05%)	1 (0·1%)	0	0	0
Pulmonary embolism	1 (0·05%)	1 (0·1%)	0	0	0
Other†	59 (2·9%)	24 (2·1%)	25 (4·5%)	7 (3·3%)	3 (3·4%)

Data are number (%) of patients with at least one specified event; if a patient had more than one complication, the highest CD score is reported. Data include all adverse events from time of surgery up to 30-days postoperatively. SG=sleeve gastrectomy. RYGB=Roux-en-Y gastric bypass. OAGB=one-anastomosis gastric bypass. CD=Clavien-Dindo. *Other procedures listed in appendix p 12. †Other complications listed in appendix p 12.

***Table*: 30-day morbidity and mortality for all patients and by bariatric procedure**

figures reported in BMS studies (0·04–0·1%)[4–6] and the 30-day mortality of about 0·1% (1/1142) with SG in this study is similar to the figure of 0·1% reported in a study of 29 588 patients.[7] In a recent systematic review,[8] 30-day complications occurred in 10·1% (319/3155) of patients who had Roux-en-Y gastric bypass (RYGB) and in 5·4% (155/2876) of patients who had SG, which is similar to the rates seen in our study (8·4% and 5·7%, respectively; table). Similarly, Stenberg and colleagues[6] reported 7·8% (196/2503) of patients with 30-day complications following RYGB.[6] The rates of 30-day severe complications (CD grade III, IV, or V) with RYGB and SG in this study (3·2% and 2·1%, respectively; table) are also similar to those reported in previous studies.[4,6,7]

Of the ten patients with symptomatic postoperative COVID-19, none needed ventilation and none died; all were CD grade I or II complications. This finding contrasts with data from the COVIDSurg Collaborative,[1] which reported pulmonary complications in half of patients undergoing various emergency or elective surgeries and a 30-day mortality of 23·8%. This striking difference is particularly notable given that obesity is associated with an increased risk of severe COVID-19, so the patients in our study might be at increased risk compared with other patients. However, unlike our study, the COVIDSurg analysis assessed surgeries done during a period early in the pandemic before local perioperative COVID-19 protocols were well established, which might help to account for the lower morbidity and mortality in our study. Another important factor in this regard might be the timing of the COVID-19. It is possible that those individuals with COVID-19 at the time of the surgery have a worse prognosis than do those who develop clinical disease several days later.

Our study included countries with variable timing of COVID-19 peak in relation to the study period. Local heterogeneity in COVID-19 prevalence might have contributed to the small number of symptomatic COVID-19 cases among the patients in our study. Notably, the few COVID-19 cases were in countries with widespread COVID-19 and other countries with widespread COVID-19 had no symptomatic cases in the study. As such, we believe that our finding of a low number of postoperative symptomatic COVID-19 cases is likely reflective of the presence and efficacy of local perioperative COVID-19 protocols.

Because of the potential for a time gap between BMS and a patient becoming infected with SARS-CoV-2, developing symptoms, requiring ventilation, and potential mortality or other outcomes, there is a possibility that some adverse outcomes that developed after 30-days might have not have been captured in the study. However, the study population was at high risk of severe COVID-19 (due to obesity, diabetes, hypertension, and cardiovascular disease) and the median incubation period for COVID-19 is about 4 days. As such, it is likely that our study identified the majority of symptomatic COVID-19 cases that developed in the study population.

Unsurprisingly, SG, RYGB, and one-anastomosis gastric bypass accounted for more than 95% of all primary procedures, which is in keeping with the last two International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) global reports.[9,10] The mean BMI of 42·4 kg/m² in our study cohort is also similar to the median of 41·7 kg/m² reported in the fourth IFSO global registry report.[9] Although we cannot rule out the possibility of selection bias caused by health-care professionals choosing lower-risk patients for BMS in view of the pandemic, the baseline characteristics of patients in our study were similar to those of other global BMS studies.[9,10]

Our study has limitations. It only included data from participating centres and might therefore not represent the complete global picture. Furthermore, although we ensured that our collaborators knew the importance of submitting all consecutive patients during the study period, we cannot be certain that all contributors followed this instruction. Our study does not have a control cohort for statistical comparison. However, a contemporary BMS control cohort would not be possible because of the international scale of the COVID-19 pandemic and comparing the safety of BMS with other surgical procedures during the pandemic was not the aim of our study. Besides, comparisons with other surgical procedures is challenging considering the different population characteristics of patients undergoing BMS. An ideal study would collect outcomes following BMS before and through the COVID-19 pandemic from the same centres for comparison. However, this approach would have been challenging due to the unpredictability and fast spread of COVID-19. The strengths of the study include the large sample size, the global reach of the study, the high data completion rate, and extensive data profiling. Additionally, the data represented different phases of the COVID-19 pandemic across the 35 included countries (before, during, or after the COVID-19 peak).

In conclusion, our study showed that 30-day morbidity and mortality following BMS during the COVID-19 pandemic with locally appropriate perioperative COVID-19 protocols in place seemed to be similar to pre-pandemic levels. However, with the evolving pandemic situation, BMS teams need to continually monitor outcome data.

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